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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,331	11/17/2003	Frederick J. Lakner	UTSJ:037US	2392
32425 7590 06/28/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER RAO, DEEPAK R	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 06/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,331

Applicant(s)

LAKNER ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 ~~are~~ are pending in the application.
- 4a) Of the above claim(s) 18-29 ~~are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 ~~are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20040217</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-29 are pending in this application.

Election/Restrictions

Applicant's election of Group I (claims 1-17 drawn to compounds) in the reply filed on April 16, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on April 16, 2007.

The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the merits on the elected claims would be final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art

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search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

In response to the election of a single compound (or a set of compounds), applicant elected "the lipoasparagine compound with a linear hydrocarbon as the R¹ group and a linear hydrocarbon as the R² group and CH₂ as the X group".

A compound falling within the elected set of compounds as indicated in the response was not found in the prior art search and the search was **expanded** to the subgenus of 'the lipoasparagine compounds with a linear hydrocarbon as the R¹ group and a linear hydrocarbon as the R² group and CH₂ or O as the X group', and art was found. Claims 1-17 read on the expanded subgenus above.

As per the guidelines of MPEP § 803.02, the Markush-type claims were examined to the extent of the searched subgenus. Claims 1-17 (all in part, drawn to generic subject matter or species **other than** as indicated above for the expanded subgenus, i.e., lipocysteine, liposerine and all other fatty amino acid derivatives; and R¹ and R² are other than a linear hydrocarbon, encompassed by the instant claims) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a Lipoasparagine (ALP) compounds (having the formula as depicted in claim 2), does not reasonably provide enablement for fatty amino acid derivatives of asparagine, cysteine or serine, or carboxylate salts thereof generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The specification fails to enable the preparation of the entire scope of the claimed compounds. The process scheme I in the specification provide the essential starting materials to prepare the claimed Lipoasparagine (ALP) compounds wherein R¹ and R² are each a linear hydrocarbon, however, there is no disclosure of the sources of starting materials needed to prepare the other fatty amino acid derivatives encompassed by the instant claims. Further, the definition of the terms R¹ and R² include ‘a cholesterol moiety, a steroid moiety, an aromatic moiety, a combination thereof, or a derivative thereof’, all of which encompass a large number of groups for which there is insufficient evidence of enablement in the specification. The

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specification provides processes of preparing the Lipoasparagine of the formula disclosed in claim 2 wherein both R^1 and R^2 represent a linear hydrocarbon, however, does not provide any explanation of what other types of compounds are intended by the instant recited "fatty amino acid derivatives"; or sources of starting materials required to prepare all types of compounds falling within the scope of the instant claims, such that a person of ordinary skill could determine if a particular compound is suitable to be a 'fatty amino acid compound' as recited in the instant claims.

The specification provides the preparation of a specific type of 'asparagine compound' (i.e., a perhydropyrimidinone compound) by cyclizing asparagine with an aldehyde R^1CHO and reacting with an acid chloride R^2XCOCl , however, does not provide any explanation or sources involved to prepare all other types of 'fatty amino acid derivatives' of the instant claims, such that a person of ordinary skill could determine if a particular group is suitable to be a 'fatty amino acid compounds' intended by the instant claims. The instant claims encompass all types of compounds, i.e., cyclic, acyclic, etc. and the specification does not enable the preparation of all types of compounds of the instant claims. It is known that a molecule containing both amine and a carboxyl functional group represents an amino acid, however, the specification does not provide sufficient guidance as to what is encompassed by the recitation of 'fatty amino acid derivative' in the claim, such that one of ordinary skill in the art could prepare the claimed compounds for the use disclosed in the specification, without having burdensome undue experimentation.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would

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take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. The starting material sources necessary to obtain the instant compounds must have been available as of the filing date in order to provide an enabling disclosure. See *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); *Ex parte Moersch*, 104 USPQ 122 (POBA 1954). Applicants should show that the sources of these starting materials was common knowledge or readily available at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In the claims, in the recitation “fatty amino acid **derivative**”, it is not clear what is intended by the term ‘derivative’. The term ‘derivative’ implies more than what is recited and/or provided in the claim or disclosure. It is suggested that the term be replaced with - - compound --.
2. In claim 2, in the definition of R^1 and R^2 , it is not clear what is intended by “a combination thereof or a derivative thereof”. It is not understood how each of the terms represent ‘a combination’ of the groups defined therein. Further, it is not understood what types of ‘derivatives’ are intended. The term ‘derivative’ implies more than what is recited and/or provided in the claim or disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 11 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al. (J. Am. Chem. Soc. 1992). The instant claims read on reference disclosed compounds, see the compounds 6 and 7 in page 1801.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-7, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (JACS 1992). The reference teaches perhydropyrimidinone compounds useful in the preparation of biologically active molecules, see the compound 7 in page 1801. Claims 1, 2, 4, 11, and 13-17 read on the reference disclosed compounds. Claims 3 and 5-7 are drawn to compounds wherein R¹ and R² are other alkyl groups, e.g., claim 3 recites 'wherein R1 and R2 are same'; claim 5 recites that 'at least one of R¹ and R² is a hydrocarbon of at least 5 carbon units'. Therefore, the instantly claimed compounds differ from the reference compounds by a -CH₂ group and it is well established that compounds that differ by a -CH₂ group are structural homologs. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference compounds to prepare the structural homolog. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are *prima facie* obvious, absent a showing of unexpected results.

Duplicate Claims

Applicant is advised that should claim 1 be found allowable, claims 13-17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 13-17 merely recite a use for the compound of claim 1, however, do not further limit the claim.

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Receipt is acknowledged of the Information Disclosure Statement filed on February 17, 2004 and a copy is enclosed herewith.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


/Deepak Rao/
Primary Examiner
Art Unit 1624

June 22, 2007